

Applicants: Robert J. Winchester, et al.
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The Claimed Invention

This invention provides a composition for treating rheumatoid arthritis comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, which amount is effective to treat rheumatoid arthritis, and (b) a pharmaceutically acceptable carrier. This composition has use in treating rheumatoid arthritis through inhibiting the SDF-1-mediated activation of a subject's CXCR4 receptors.

Formalities

Drawings

In the Notice of Draftperson's Patent Drawing Review issued concurrently with the September 11, 2002 Office Action, the Draftperson made certain objections to the drawings submitted in connection with the subject application.

In response, applicants attach hereto as Exhibit B 19 sheets of new, corrected formal drawings for Figures 1-12.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 7, 11, 12, 16 and 17 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants point out that claims 7, 11, 12,

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16 and 17 have been canceled and new claims 18 and 19 have been added. Accordingly, applicants understand the Examiner's rejection as directed to new claims 18 and 19.

Specifically, the Examiner asserted that "the claims encompass a vast array of agents with undefined structure wherein the structure of said agents is not disclosed in the specification." The Examiner further asserted that "the only nonpeptidyl agent disclosed in the specification is a bicyclam."

In response, applicants respectfully traverse. Applicants point out that new claim 18 (and claim 19 depending therefrom) provides that the composition for treating rheumatoid arthritis comprises a *bicyclam* capable of inhibiting the activation of the CXCR4 receptor by SDF-1 and a pharmaceutically acceptable carrier. As the Examiner acknowledges, bicyclams are described in the specification, and thus, applicants maintain that the specification conveys to one skilled in the art that applicants were in possession of the claimed composition.

In view of the above remarks, applicants maintain that new claims 18 and 19 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102(a)

The Examiner rejected claims 7, 11, 12, 16 and 17 under 35 U.S.C. §102(a) as allegedly anticipated by Schols, et al. (Antiviral Research 35, 147-156, 1997). Applicants point out that claims 7, 11, 12, 16 and 17 have been canceled and new claims 18 and 19 have

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been added. Accordingly, applicants understand the Examiner's rejection as directed to new claims 18 and 19.

In response to the Examiner's rejection, applicants respectfully traverse.

Again, new claims 18 and 19 provide a composition for treating rheumatoid arthritis comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, which amount is effective to treat rheumatoid arthritis, and (b) a pharmaceutically acceptable carrier.

To anticipate the instant compositions, Schols, et al. would have to teach each and every element thereof. They fail to do this.

Schols, et al. teach that the bicyclam AMD3100 interacts with the CXCR4 receptor and prevents both infection of CXCR4-positive cells with T-tropic HIV-1 and specific binding of CXCR4 receptor with an anti-CXCR4 monoclonal antibody (12G5).

Schols, et al. do not, however, teach a composition comprising a pharmaceutical carrier and a bicyclam in an amount effective to treat rheumatoid arthritis. Schols, et al. therefore fail to teach each and every element of the rejected claims.

In view of the above remarks, applicants maintain that new claims 18 and 19 satisfy the requirements of 35 U.S.C. §102(a).

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Rejections Under 35 U.S.C. §102(b)

The Examiner rejected claims 7, 11, 12, 16 and 17 under 35 U.S.C. §102(b) as allegedly anticipated by De Vreese, et al. (Antiviral Research 29, 209-219, 1996) and Murrer, et al. (U.S. Patent No. 5,021,409). Applicants point out that claims 7, 11, 12, 16 and 17 have been canceled and new claims 18 and 19 have been added. Accordingly, applicants understand the Examiner's rejections as directed to new claims 18 and 19.

In response to the Examiner's rejections, applicants respectfully traverse.

New claims 18 and 19 are described above.

To anticipate the claimed composition, both De Vreese, et al. and Murrer, et al. would have to teach each and every element thereof. They fail to do this.

De Vreese, et al. teach that bicyclams inhibit HIV-1 infection by interfering with virus-cell fusion (i.e., viral entry). Murrer, et al. teach that certain bicyclam compounds have potential in treating AIDS and other retroviral infections.

Neither De Vreese, et al. nor Murrer, et al., however, teach a composition comprising a pharmaceutical carrier and a bicyclam in an amount effective to treat rheumatoid arthritis. Murrer, et al. and De Vreese, et al. therefore each fail to teach each and every element of the rejected claims.

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In view of the above remarks, applicants maintain that new claims 18 and 19 satisfy the requirements of 35 U.S.C. §102(b).

Summary

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the \$465.00 extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231.

Alan J. Morrison
Reg. No. 37,399

Date

3/11/05

Page 1, lines 7-11:

This application is a continuation-in-part application of International Application No. PCT/US99/17178, filed July 29, 1999, which claims priority of U.S. Serial No. 09/127,651, filed July 31, 1998, now abandoned, the contents of which are hereby incorporated by reference into this application.